JUN - 9 2000

NDA 18-961/S-009

Abbott Laboratories
Attention: Chris Markos
Manager, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road, D-389, AP30
Abbott Park, IL 60064-3537

Dear Mr. Markos:

Please refer to your 'Changes Being Effected' supplemental new drug application dated July 3 1, 1998, received August 4, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chromic Chloride Injection.

This supplemental new drug application provides for a labeling revision in response to the final rule, effective August 27, 1998, entitled *"Specific Requirements on Content and Format of Labeling for Human Drugs: Addition of Geriatric Use Subsection in the Labeling."* More specifically, the proposed labeling revision is as follows:

To the **PRECAUTIONS** section of the package insert, the following paragraph has been added:

> **Geriatric Use:** An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.